DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

July 28, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Buena Suerte Veterinary Services, LLC
Leonard P. Blach, DVM
Rt. 3, 1907 Whitemill Road
Roswell, New Mexico 88201

Ref. #: DEN-00-28

Dear Dr. Blach:

This letter is written to address the seriousness of actions in your veterinary practice, and the public health concerns, as a result of drug treatment of several cows with gentamicin preparations you compounded and which were used in an extralabel manner.

Between March and June of 1999, USDA/FSIS found gentamicin residues, for which there is no tolerance in edible tissues, in numerous cows from several Chaves County, New Mexico dairy operations. In follow-up to these residues Investigators from this office conducted inspections of [redacted] of these dairies[1] in August and December1999. These inspections confirmed the gentamicin residues found by USDA/FSIS in 21 of these cows were caused by the use of Buena Suerte BS-Clear Mastitis Medication.

Investigators Barbara J. White and Margaret M. Annes conducted an inspection of your veterinary practice during the week of August 8, 1999. The inspection confirmed you compounded Buena Suerte BS-Clear in your clinic from Gentocin, Dexamethasone, and Neomycin P.S.S., as a mammary infusion medication for mastitis treatment. The drug Gentamicin Sulfate Solution, which you use to compound BS-Clear, is labeled for use in horses not intended for food, thus its use as a mammary infusion in dairy cows is an extralabel use. The inspection also confirmed you prescribed Buena Suerte BS-Clear to your clients, including the [redacted] dairies mentioned above.

Our investigation of your veterinary practice also concluded that you do not generally examine animals to be treated with this or other medications; you are not a staff veterinarian at these dairies and do not make regularly scheduled exams of cows in these herds; you do not assure that extralabel drugs (i.e. BS-CLEAR) are used in an appropriate manner; and you do not maintain records or assure that your clients maintain records relating to extralabel drug use of unapproved drugs.

1. [redacted]

PURGED

You should be aware of the limitations and conditions established for extralabel drug use or intended extralabel use in animals [Title 21 Code of Federal Regulations, Part 530 - Extralabel Drug Use in Animals (21 CFR 530)], a copy of which was provided to you by the investigators during the inspection of your practice. A valid veterinarian-client-patient relationship must be established, and a careful diagnosis and evaluation of the conditions for which the extralabel drug is to be used, must be made by the veterinarian. The limitations established (21 CFR 530.11) do not permit extra-label use resulting in any residue above an established tolerance (There is no tolerance for gentamicin, therefore, any residue is a violation). The extralabel use criteria requires that a substantially extended withdrawal period be established for edible products of food animals. The withdrawal period is to be supported by appropriate scientific information, and the veterinarian is required to maintain records of the specified withdrawal. For your information, these records should indicate: identification of the animal, condition treated, dosage administered, treatment duration, and withdrawal time to be observed. Additionally, the veterinarian is required to take appropriate measures to assure that assigned time frames for withdrawal are met and that no illegal drug residues occur. Your failure to meet these requirements results in the violation of Section 501(a)(5) of the Federal Food, Drug & Cosmetic Act (the Act) (new animal drug adulteration) rendering the drug unsafe within the meaning of Section 512 of the Act.

The presence of gentamicin in edible tissues from these animals further causes the adulteration of food (the edible tissues of a slaughtered cow) in violation of Section 402(a)(2)(C)(ii) of the Act since it bears or contains a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the Act.

The above is not intended to be construed as an all-inclusive list of violations. As a veterinarian to producers of animals that are offered for sale as food, you are also responsible for assuring that your veterinary drugs and treatments comply with the law. You should take prompt action to correct the deviations encountered, and assure that your future actions in the administration of veterinary drugs to food producing animals of your clientele, do not result in animal tissues bearing violative residues of public health significance.

At the completion of our inspection, you advised the investigators that you had visited [redacted] and had retrieved all BS-CLEAR from them and subsequently destroyed those medications. You also advised that you had discontinued manufacture of Buena Suerte BS-CLEAR until you re-evaluate the preparation. We also acknowledge your letter of October 20, 1999, which further states that you have discontinued the use of this product until a complete investigation is conducted. What is your future intent for BS-Clear? We are also concerned with your extralabel use of Tiamulin, a swine product, and Amiglyde, a new animal drug not approved for use in food animals. These products are currently not included in FSIS testing programs and could be causing additional residues, which could be of public health concern. What is your future intent for these and any other medications that you prescribe for extralabel use?

Failure to correct the conditions of your veterinary practice and to establish procedures whereby such conditions do not recur may result in regulatory action without further notice, such as seizure and/or injunction.

We recognize this letter is not timely to the immediate findings of our investigation into these illegal drug residues. We believed it necessary to monitor FSIS residue testing in the Chaves County area prior to issuing this Warning Letter to insure the matter had been appropriately resolved.

You should notify this office, in writing, within 15 working days of receipt of this letter, of specific steps you have taken or are taking to correct the noted violations and to bring your operation into compliance with the law. This response should include an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Please include copies of any available documentation that demonstrates that corrections have been made.

A copy of this letter is being sent to the New Mexico Livestock Board for whatever action they may deem appropriate.

Please direct your written response to the attention of H. Tom Warwick, Compliance Officer, Food & Drug Administration, P.O. Box 25087, Denver, Colorado 80225-0087. Verbal questions may be directed to him at (303) 236-3054.

Sincerely,

Thomas A. Allison
District Director

cc: Ronald K. Jones, DVM
Boulder District Manager
USDA / FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

John F. Wortman Jr.
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New Mexico Livestock Board
300 San Mateo N.E., Suite 1000
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